DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93275d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2953289

May 2, 2002

Joseph A. Caito, President
Caito Fisheries, Inc.
19400 South Harbor Drive
Fort Bragg, California 95437

WARNING LETTER

Dear Mr. Caito:

On January 15, 22, and February 1, 2002, we inspected your seafood processing facility located at Pier 45, Shed B-6/B-7, San Francisco, California, and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your tuna and ready-to-eat crab fishery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA 483 and discussed them with Michael G. Gutierrez, Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your ready reference. Your serious HACCP deviations are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met at each critical control point, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Tuna lists a critical limit at the Receiving CCP that is not adequate to control histamine formation for

Tuna received directly from the harvest vessel. To ensure that the tuna fish or other histamine producing species were handled safely during harvest and while on-board the fishing vessel, FDA recommends that you supplement your internal temperature critical limit with sensory examination of the fish and receipt of harvest vessel records that show proper on-board handling with every lot received. At a minimum, the harvest vessel records should include the following information: method of capture, date and time of landing, estimated time of death, air/water temperatures, method of cooling, date/time cooling began, cooling rate, storage temperature, date and time of off-loading. The VSOP certification record is not sufficient. Alternatively, histamine testing of the fish at receipt can be conducted instead of obtaining harvest vessel records. Please refer to Chapter 7 of FDA's Fish & Fisheries Products Hazards & Controls Guidance, 3rd Edition for information on strategies to control histamine formation.

2. You must have a HACCP plan that lists the monitoring procedures for each critical control point to ensure compliance with critical limits, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plans for "Tuna" and "Cooked Dungeness Crab" list monitoring procedures and frequencies at the Cooler Storage CCP that are not adequate to control the food safety hazards associated with these products (histamine formation and pathogens respectively). During refrigerated storage of these products, FDA recommends maintenance of refrigerated storage coolers at 40°F or below, with continuous monitoring of the temperature. Alternatively, if the stored fish and fishery products are maintained on ice or chemical cooling media, FDA recommends that the adequacy of ice or cooling media be controlled with visual checks at least twice a day.

Sufficient time has passed, since our inspection of January 2002 and our presentation of the FDA 483 Inspectional Observations to Mr. Gutierrez, to correct the violations at your facility. If you have not made corrections, you must immediately take appropriate steps to correct the violations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response

documentation such as copies of the revised HACCP plans, temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Charles D. Moss Acting DD

for Dennis K. Linsley
District Director
San Francisco District

Enclosures:

Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

cc: Michael G. Gutierrez, Manager
Caito Fisheries, Inc.
Pier 45, Shed B-6/B-7
San Francisco, California 94133